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Report Highlights:

There are three events approved for commercialization in Uruguay: one soybean variety (MON 40-3-2) and two corn varieties (MON 810 and Bt 11). On January 29th, the Uruguayan President signed a decree imposing a moratorium for 18 month on review and approval of new events.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
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Executive Summary

Uruguay now ranks 10th among countries in the number of acres planted with biotech varieties, as production of crops has increased in recent years.

The President of Uruguay signed a decree imposing a de facto moratorium for 18 month on the review and approval of new events on January 29, 2007. A new committee in charge of reviewing a proposal for a new regulatory framework was created at the same time. One of main objectives of this new approach is to allow more participation of all interested parties.

The Government of Uruguay (GOU) first formally endorsed the use of biotechnology and took concrete steps towards the oversight and regulation of biotechnology products by creating a risk assessment commission for genetically modified organisms (GMOs) in 1995. The first biotech authorization was in 1996 when the use of biotech soybeans was authorized. In 2000, Decree 249/00 created the Risk Assessment Commission of Genetically Modified Plants (CERV) and established a regulatory framework to authorize the introduction, use and manipulation of GMOs.

There are currently no requirements for labeling of biotech products, nor are there laws or regulations governing the use of labels such as “non GMO” or “biotech free”.

Production

Authorized Biotech events for production and commercialization are:

Soybeans, event 40-3-2 (approved 1996)

Corn, event MON 810 (approved 2003)

Corn, event Bt 11 (approved 2004)

Soybeans

Soybean harvested area increased from 77,000 hectares in MY2002/03 to over 420,000 hectares in MY2006/07. Approximately 99 percent of total soybean area is planted with Round-up Ready soybeans. Potential area for increased soybean production is fairly limited compared to neighboring countries.

Corn

The authorization for imports and commercialization of Monsanto’s insect-resistant corn (variety MON 810) was released by the GOU in 2003. Bt 11 corn was approved in 2004. The approval of both varieties aroused opposition among environmentalists and other groups.

Evolution of area planted (conventional corn and Bt)

Year	Total Area (has)	Bt Area (has)
2003	44,923	1,150
2004	60,601	23,300
2005	53,400	30,000
2006	85,000	46,000
2007/08*	170,000	105,000

* Estimated

Rice

No biotech rice varieties have been approved. Adoption in Uruguay of rice varieties containing biotech events will depend, almost exclusively, on the acceptance of these events in Uruguay's export markets. Rice producers are very open to the idea of biotechnology, but they are unlikely to adopt new technologies that may jeopardize their export markets.

Moratorium for new Biotech Events

On January 29th, 2007, the GOU decreed "the suspension of evaluation of new requests of authorization to introduce events of living organisms of vegetal origin and their genetically modified parts, for any of the purposes defined in decree 249/2000, by the Commission of Risk Assessment of Genetically Modified Vegetables". The moratorium applies to the introduction of new biotech events for both production and field testing.

During this period, a group composed of representatives of different Ministries (Agriculture, Health, Economy and Environment) will re-evaluate and strengthen the current policy, with different social sectors. The area of work covers the following areas: social issues, scientific research and agricultural production. The timeframe for the re-evaluation process is set for 18 months. Including the previous suspension of the approvals in 2006 until the National Coordination Committee (CNC) developed a proposal for a biosafety framework (see Policy), it implies that for at least 3 years Uruguay will not approve or do field tests on new events.

Uruguay has experienced in the last five years a real agricultural revolution, with crop area estimated for this year of 470,000 HAS, several times the area registered in 2000/2001. Sustained world-wide demand and the favorable local conditions to the expansion of the crops (available land, efficient technicians and companies, stability of the business framework) are key causes of the phenomenon. The suspension of new approvals is currently having its largest impact on corn production, since new varieties suitable for conditions in Uruguay are not being approved.

According to the survey conducted on 2006 (see page 10), 8 out of 10 producers think that biotech seeds are positive or very positive for production, and 7 out of 10 think that biotech seeds are positive for the country.

Policy

As noted above, approvals are suspended for another six months pending review of a new regulatory system that was proposed at the end of 2006 by the National Coordination Committee (CNC). The CNC was formed by the GOU to develop a new regulatory framework. Approval of new events was suspended until the committee provided its report. The 18-month moratorium decreed on January 29, 2007 is to provide time to review the recommendations of this committee.

The CNC included representatives of all interested parties in aspects related to biosecurity (23 organizations were represented), such as NGOs, environmental groups and producer associations. The CNC evaluated the following areas:

- Evaluation of environmental impact,
- Evaluation of effects in human health,
- Evaluation of socioeconomic impact,
- Evaluation of utilization of biotech seeds,
- Research and development,
- Cover administrative aspects.

Pending implementation of the new regulatory framework, oversight and regulatory responsibilities are currently vested in the Risk Assessment Commission of Genetically Modified Plants (CERV), which is headed by the Ministry of Livestock, Agriculture and Fisheries (MGAP.) Member organizations also include the Ministry of Housing, Land Management and the Environment, the Ministry of Public Health, the National Seed Institute; and the National Agricultural Research Institute. The Commission is responsible for considering, on a case-by-case basis, the potential risks and benefits of each new biotech product.

Biosafety regulations were established following the mandate of the Convention of Biological Diversity. At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for "sustainable development". One of the key agreements adopted at Rio was the Convention on Biological Diversity. The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. Uruguay (along with Chile and Costa Rica) adapted this legislation for its seed and plant health inspection services.

The regulatory procedure, which does not cover laboratory research, does include risk assessment and risk management. It includes consultation with a broad range of specialists and stakeholders (social scientists and representatives of civil society) apart from those usually included (toxicologists, nutritionists, molecular biologists, and plant breeders). The final decision on the release of biotech seeds, however, falls within the scope of both the MGAP and the Ministry of Economics and Finance.

Main duties of the Risk Assessment Commission include:

1. To create the rules to perform the risk assessment for the introduction, use, and manipulation of biotech seeds and their parts,

2. To analyze case by case, using sound science, the risk inherent in each product,
3. To provide advice to the competent authorities (Ministry of Livestock, Agriculture, and Fisheries, and the Ministry of Economy and Finance) regarding authorizations,
4. To advise the competent authorities about risk management and communication measures to be adopted in each case; and,
5. To advise the Uruguayan Government (GOU) about biosafety.

The Risk Assessment Commission can create working groups for specific tasks when necessary and request technical advice from universities and public or private research centers, as well as of independent specialists recognized by their technical proficiency.

The commission includes representatives of the following ministries:

1. Ministry of Livestock, Agriculture and Fisheries (this representative occupies the presidency of the Commission),
2. Ministry of Environment (this representative occupies the vice presidency of the Commission),
3. Ministry of Public Health,
4. National Seed Institute (INASE); and,
5. National Agricultural Research Institute (INIA).

Approvals from Argentina, United States and Canada are taken into account as a precedent in the approval evaluation process.

Cartagena Biosafety Protocol

Uruguay has yet to ratify the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD). Up until the Protocol's entry into force (September 2003) Uruguay operated within the framework of the GRULAC Group (Group of Latin American and the Caribbean Countries) in pursuing the implementation of the biosafety principles outlined in the Cartagena Protocol.

Uruguay, a member of the former Miami Group, has strongly concurred with USG positions on biotech at international fora in the past, and is highly likely to continue to do so.

Traceability and labeling

Issues related to biotechnology such as traceability and labeling (T&L) of biotech seeds are currently the focus of an internal debate that is being carried out at the governmental level.

With respect to the European Union's T&L regulations, MGAP contacts report that traceability is a difficult issue since the issue is commercial, rather than scientific. These contacts report that since Uruguay is very dependent on the European market as an outlet for its agricultural products, some kind of traceability system will probably be necessary. However, they have repeatedly made it very clear that the GOU would not support mandatory requirements in international fora.

With regard to labeling of biotech products, contacts in the GOU indicate that the GOU is still reviewing this issue. It appears that the position of the MGAP is that labeling should be mandatory for products that are substantially different from their original version, and for those products with a lower safety threshold.

There are currently several draft bills in the legislature to require the mandatory labeling of products containing genetically modified components.

Stacked genes

No policy. A stacked event is considered to be a whole new event, and it must undergo a full review.

Coexistence

No policy. The European Union's regulations are currently being used on an informal basis, but adapted to Uruguay.

Refuges

It is mandatory that 10% of the planted area be kept as a refuge. Uruguay is a small country and the National Seed Institute (INASE) visits the producers in person, thus maintaining a strict control.

Royalties

All seeds pay extended royalties and the seed law makes a provision for the use of seed the following year. The seed companies require producers to sign a contract promising to pay royalties the next year.

Trade Barriers / Pending legislation

The current government, favors full "end-product" and "process-based" labeling. On several occasions during the past administration the opposition publicly urged the former president to halt the liberalization of transgenic crops, based on the country's goal of becoming a "natural country" and on the application of the precautionary principle.

Marketing

There is still misunderstanding and misperception about the safety of biotech plants and foods on human health or in the environment. NGOs have opposed the introduction of biotech crop planting and strongly request labeling on biotech products. There is a scattered, albeit unorganized movement against biotechnology, led by NGOs. A major issue is the potential conflict between biotech crops and the marketing campaign for products from Uruguay as "Uruguay Natural".

Consumer associations have raised concerns about possible negative impacts on human health and the environment. They mainly advocate labeling and traceability and local field trials of biotech seeds prior to approval. They also question the potential for toxicity and allergenicity of biotech products.

There is some resistance in the meat industry to the approval of White Clover, one of the events that was under research before the moratorium. Clover is used in pastures, and for this reason “natural meats” will cease to be reliably “natural” according to their arguments. The largest potential issue in this area is for the sheep industry. Clover is used to feed sheep exported to Arab countries, where biotechnology is highly controversial.

There are no relevant, specific studies on the marketing of biotechnology products in the country.

The Uruguayan Seed Chamber has conducted a survey among farmers on the use of Bt corn seed that provided the following conclusions:

- Bt corn has a high penetration level (67% of total area planted),
- Bt seed provides good performance compared to conventional seed,
- Total cost of pest control is lower with the utilization of Bt corn,
- 86% of consulted farmers are more satisfied with the pest control with Bt seed than conventional seed,
- 9 out of 10 farmers do not report any damage related to the use of Bt corn,
- 100% of consulted farmers use refuges,
- 30% of consulted farmers plans to increase the area dedicated to Bt corn, 50% reported they will maintain the same area, and 18% reported will diminish the area (the reasons voiced are not related to Bt seed),
- Farmers are even more optimistic when talking about the future of Bt seeds. 86% believe that global area planted will increase in the next 5 years, and 66% of them reported that they will personally increase the use of Bt seed in that timeframe.

Capacity Building and Outreach

2002

- A. FAS Buenos Aires organized a biotechnology seminar in Uruguay that was successful in terms of attendance (over 300 participants).
- B. Through Cochran funds, FAS Buenos Aires sponsored two-week biotechnology training in the United States for 3 Uruguayan Government officials, organized by ICD/FAS and Michigan State University.

2004

- A. FAS Buenos Aires selected 2 Uruguayan journalists that participated in a US Grains Council activity in Hawaii, where they learnt about the papaya industry.
- B. The Agricultural Counselor accompanied State's Biotech Negotiator to Uruguay to participate in a series of round tables on biotechnology organized by Embassy Montevideo.
- C. Through Cochran funds, FAS Buenos Aires sponsored two-week biotechnology training in the United States for 1 representative of the Uruguayan Seed Chamber, organized by ICD and Michigan State University.
- D. Two Uruguayan producers attended the Farmer-to-Farmer workshop at the University of Zamorano in Honduras.
- E. FAS Buenos Aires sponsored the trip of an Argentine expert to participate in a seminar in Santiago, Chile, directed to the Chilean Parliament.

2005

- A. The Agricultural Counselor accompanied the Department of State's Biotech Negotiator to Uruguay to participate in a series of round tables on biotechnology organized by Embassy Montevideo.
- B. FAS Buenos Aires in concert with FAS Santiago organized and accompanied a Southern Cone Congress Delegation to the United States, to demonstrate how the United States uses and regulates agricultural biotechnology.

2007

- A. FAS Buenos Aires along with the Uruguayan Seed Chamber organized a two-day conference directed mainly to Congressmen, but also to media, academia, government officials and public in general.

Proposed Activities

FAS Buenos Aires proposes a continuation of education and outreach as well as a more targeted information campaign. Specific activities may include:

- Workshops in different cities to target audiences around the country,
- Coordination with local universities to demonstrate the benefits of Biotechnology in Uruguay,
- Continue Cooperator, Cochran and International Visitor program activities,
- Special activities designed for Consumer Association leaders and consumers in general,

- Workshop especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products; and,

- Workshop on risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.